

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION**

MATTHEW GERBER, §
§
Plaintiff, §
§
v. § CIVIL ACTION NO. H-03-1886
§
HOFFMAN-LA ROCHE INC., §
§
Defendant. §

MEMORANDUM AND ORDER

The Court, in a Memorandum and Order issued on May 20, 2005, granted Defendant Hoffman-La Roche's Motion for Summary Judgment [Doc. # 23], dismissing Plaintiff Matthew Gerber's claim to recover damages for Defendant's design, manufacturing, and marketing its prescription drug Accutane. Pending before the Court is Plaintiff Matthew Gerber's Motion for Reconsideration of Summary Judgment and Request for Hearing and Memorandum in Support [Doc. # 62] ("Plaintiff's Motion") filed pursuant to Federal Rule of Civil Procedure 59(e). Having considered the parties' submissions, all matters of record, and the applicable legal authorities, the Court concludes that Plaintiff's Motion should be **denied**.

I. STANDARDS GOVERNING RECONSIDERATION

A motion to reconsider under Rule 59(e) "must clearly establish either a manifest error of law or fact or must present newly discovered evidence." *Schiller v.*

Physicians Res. Group, Inc., 342 F.3d 563, 567 (5th Cir. 2003). Motions to alter judgment “serve the narrow purpose of allowing a party to correct manifest errors of law or fact or to present newly discovered evidence.” *Waltman v. Int'l Paper Co.*, 875 F.2d 468, 473 (5th Cir. 1989) (citation omitted); *see also Westbrook v. Commissioner of Internal Revenue*, 68 F.3d 868, 879 (5th Cir. 1995) (“Reconsideration of proceedings is generally denied in the absence of ‘substantial error’ or ‘unusual circumstances.’”); *Texas Instruments, Inc. v. Hyundai Elec. Indus.*, 50 F. Supp. 2d 619, 621 (E.D. Tex. 1999); *Lupo v. Wyeth-Ayerst Lab.*, 4 F. Supp. 2d 642, 645 (E.D. Tex. 1997); *Resolution Trust Corp. v. Holmes*, 846 F. Supp. 1310, 1316 (S.D. Tex. 1994) (Lake, J.). To satisfy this standard, Plaintiffs must “point to controlling decisions or data that the court overlooked that might alter the conclusion reached by the court.” *Shrader v. CSX Transp., Inc.*, 70 F.3d 255, 257 (2d Cir. 1995). “Neither a Rule 59 nor a Rule 60 motion provides the proper vehicle for rehashing old arguments.” *Holmes*, 846 F. Supp. at 1316 (S.D. Tex. 1994); *see also Durkin v. Taylor*, 444 F. Supp. 879, 889 (E.D. Va. 1977) (Rule 59(e) is not intended “to give an unhappy litigant one additional chance to sway the judge.”).

II. DISCUSSION

Plaintiff asserts that reconsideration is warranted because the Court improperly: (1) decided the adequacy of the package insert warning as a matter of law, (2) weighed

evidence contrary to proper summary judgment procedure, and (3) sustained Defendant's objections to Plaintiff's use of the June 2002 Accutane label as a subsequent remedial measure. The Court addresses each of these arguments below.¹

A. Adequacy of the Warning as a Matter of Law

Plaintiff argues that the adequacy of a warning is always a fact issue for the jury and never a question of law for the Court. Plaintiff criticizes the line of cases cited by the Court in its May 20 Order and Memorandum and contends that the Texas Supreme Court's holding in *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 592 (Tex. 1986), requires that a jury must always decide the issue. The Court agrees that, generally, under Texas law the adequacy of a warning is a question of fact to be determined by a jury. However, the Court in *Alm* was not presented with an argument that the warning at issue was adequate as a matter of law. Moreover, the prescription drug context of this case resembles the contexts of recent cases from the Fifth Circuit and Texas appellate courts, which have stated that an inadequate warning is not always a jury issue. See *Stahl v. Nocartis Pharm. Corp.*, 283 F.3d 254, 264 (5th Cir. 2002); *Wyeth- Ayerst Lab. Co. v. Medrano*, 28 S.W.3d 87, 95 n.6 (Tex. App. –Texarkana

¹ Plaintiff submits several exhibits in support of his reconsideration motion. There appears to be no reason that these exhibits could not have been submitted in connection with Plaintiff's responses to the summary judgment motion. These exhibits are not timely and are stricken.

2000, no pet.); *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App. – Waco 1993, writ denied); *see also McNeil v. Wyeth Am. Home Prods. Corp.*, 2005 WL 544222 *4, *6 (N.D. Tex. Mar. 4, 2005); *Brumley v. Pfizer*, 149 F. Supp. 2d 305, 310 (S.D. Tex.) (Jack, J.). Plaintiff has not presented any factually similar authority contrary to these cases, nor has he presented any authority that suggests—on facts similar to those presented in this case—that the Court’s ruling on the legal adequacy of the label is erroneous.

B. Weighing of the Evidence

Plaintiff further contends that the Court failed to consider conflicting evidence in the light most favorable to the plaintiff, and specifically focuses on Dr. Michael Coverman’s deposition testimony. Plaintiff asserts that Dr. Coverman’s testimony is clear and unambiguous evidence that Defendant’s warnings were inadequate.² The

² Dr. Coverman testified:

- Q. All right. Now, you’re looking at Deposition Exhibit 2, which is August 1983 prescribing information for Accutane. Correct?
- A. Yes.
- Q. Does that document, the August 1983 prescribing information for Accutane, adequately inform you of how to use this drug safely?
- A. No.
- Q. Why does it not?
- A. It doesn’t address monthly pregnancy monitoring. It doesn’t address a double method of birth control. And those are the two primary, the primary and secondary. I call it a double method. You refer to it as primary and secondary methods. It doesn’t address that at all.

(continued...)

Court was aware of and addressed Dr. Coverman's testimony when issuing the May 20 decision, and considered Dr. Coverman's after-the-fact deposition statements in the light most favorable to Plaintiff.³ Nevertheless, these comments do not raise a genuine issue of material fact on the claims Plaintiff asserts. First, the testimony is primarily probative on a wrongful birth theory, which Plaintiff implicitly acknowledges is not

² (...continued)

* * * *

- Q. Would you prescribe this drug to Ms. Gerber today, knowing what you know today?
- Q. I am not talking about the medical reasons.
- A. Yeah.
- Q. I am talking about her condition as far as birth control.
- A. Well, *if Ms. Gerber said, I will not or cannot use a secondary method beyond just my hormonal method—beyond for whatever reason couldn't or wouldn't*, I would not give it to her today.
- Q. So your answer is no, you would not prescribe Accutane to Ms. Gerber or any other patient that was just on an IUD *and could not or would not use another form of birth control?*
- A. That is correct.
- Q. If Roche had given you those warnings saying that patients – I am talking about in November of '83 – patients must be on two forms of birth control. They must have monthly pregnancy tests, and any form of birth control can fail, would you have prescribed Accutane to Ms. Gerber in the condition she was in?
- A. And again, I am sorry, but when you say “the condition,” meaning only on the IUD?
- Q. Correct.
- A. Correct. I would not.

Deposition of Dr. Michael Coverman, Dec. 10, 2004, at 54-57 (emphasis added).

³ The Court also was aware of and considered the affidavit of Dr. Alan S. Boyd, and his conclusory opinion that “the warnings in the 1983 Accutane package insert were inadequate to warn physicians of the risks attendant with its use in women of child bearing potential and inform the physician of safe methods for its use.”

legally viable. The relevance of the doctor requiring Shirley Gerber's use of a second birth control method is that Plaintiff would not have been conceived. Further, the answer on which Plaintiff relies is premised on facts not supported by the record. There is no evidence that if Dr. Coverman had counseled Shirley Gerber to use two forms of birth control she would have refused and instead opted not to use Accutane at all. There is no basis for speculating that Shirley Gerber would have chosen to forego Accutane therapy rather than following the instruction advocated by Plaintiff. Thus, it is not a reasonable inference that the suggested alternative warning would have altered Dr. Coverman's decision to prescribe the product to Shirley Gerber in 1983, or that Shirley Gerber would have changed her decision to take Accutane. Finally, Dr. Coverman's response to leading questions about what, in retrospect, he might have done differently on birth control counseling or testing had there been more detailed precautions included in the Accutane package insert is speculation. Thus, Plaintiff has not produced evidence sufficient to raise a genuine fact issue that the alleged inadequacy of the package insert caused Mr. Gerber's birth defects.

C. Subsequent Remedial Measures as Evidence

Plaintiff asserts that the Court erred in excluding the June 2002 prescribing information because subsequent remedial measures not voluntarily undertaken by a defendant fall outside of the provisions of Rule 407 of the Federal Rules of Evidence.

However, the cases on which Plaintiff rely are materially factually dissimilar from the circumstances at bar. They involve subsequent remedial repairs, rather than warnings. More significantly, Plaintiff's cited cases do not reflect the more recent pertinent rulings of the Fifth Circuit and another federal appellate court. *See Stahl*, 283 F.3d at 270 n.10 (holding that subsequent warning label was not admissible under Federal Rule of Evidence 407); *see also Werner v. Upjohn Co.*, 628 F.2d 848, 859 (4th Cir. 1980) ("FDA regulations in the area of drug labeling do not require a new exception to Rule 407"). None of Plaintiff's arguments concerning the FDA's role in Defendant's decision to implement subsequent remedial measures persuades the Court that it erred in excluding the June 2002 labeling information.

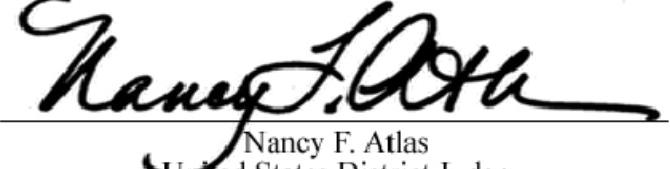
III. CONCLUSION

Plaintiff's Motion for Reconsideration fails to raise any persuasive or new arguments. It is therefore

ORDERED that Plaintiff's Motion for Reconsideration [Doc. # 62] is
DENIED. It is further

ORDERED that Plaintiff's new exhibits submitted in connection with his Motion for Reconsideration are **STRICKEN as untimely**.

SIGNED at Houston, Texas this **1st of July, 2005**.



Nancy F. Atlas
United States District Judge